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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/761,557

01/21/2004

D. James Surmeier

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MEDLEN & CARROLL, LLP  
101 HOWARD STREET  
SUITE 350  
SAN FRANCISCO, CA 94105

EXAMINER

CHONG, KIMBERLY

ART UNIT

PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/761,557

Applicant(s)

SURMEIER ET AL.

Examiner

Kimberly Chong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4, 10 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 10, 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 12/22/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 02/21/2006 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 12/22/2006, claims 4, 10 and 17 are pending in the application.

### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 10 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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Claims 4, 10 and 17 are drawn to a method manipulating neuronal ion channels comprising transfecting a cell that expresses an mRNA encoding a Kv3.4 protein with a vector encoding an siRNA directed against said mRNA encoding a Kv3.4 nucleic acid wherein said siRNA is complementary to a portion of SEQ ID No. 6, wherein said portion of SEQ ID No. 6 is the portion of SEQ ID No. 6 starting with SEQ ID No. 3 and ending with SEQ ID No. 4 and wherein said siRNA is capable of inhibiting Kv3.4 expression in said cell and wherein said cell is located *in vitro* or *ex vivo*.

The specification, on page 67, discloses double stranded RNAs targeting different target sites of Kv3.4 nucleic acid sequence having SEQ ID Nos. 1, 2, 3, 4 or 5. The specification does not, however, disclose dsRNAs targeting a range starting at SEQ ID No. 3 and ending at SEQ ID No. 4 as recited by the instant claims.

If Applicant believes that such support is present in the specification and claimed priority documents, Applicant should point, with particularity, to where such support is to be found.

Therefore, the priority date granted to claims 4, 10 and 17 is 01/21/2004, the filing date of the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al. (J Oral Pathol Med. 2003, 32: 606-11, Low et al. (US Patent 6,071,891), Hammond et al. (Nature Reviews Genetics 2001, Vol. 2: 110-119) and Tuschl et al. (WO 02/44321).

Claims 4, 10 and 17 are drawn to a method manipulating neuronal ion channels comprising transfecting a cell that expressed an mRNA encoding a Kv3.4 protein with a vector encoding an siRNA directed against said mRNA encoding a Kv3.4 nucleic acid wherein said siRNA is complementary to a portion of SEQ ID No. 6, wherein said portion of SEQ ID No. 6 is the portion of SEQ ID No. 6 starting with SEQ ID No. 3 and ending with SEQ ID No. 4 and wherein said siRNA is capable of inhibiting Kv3.4 expression in said cell and wherein said cell is located *in vitro* or *ex vivo*, wherein the cells are transplanted back into a subject.

Chang et al. teach an antisense compound complementary to a Kv3.4 nucleic acid having SEQ ID No. 6 (see page 608, column 1). The specification at page 19 defines the term 'complementary' to mean a sequence that is complementary to another sequence can have only some of the nucleic acids based paired with the nucleic acids of another sequence. Thus, the antisense compound taught by Chang et al. has six nucleic acid sequences that are based paired to SEQ ID NO. 6 in the portion starting with SEQ ID No. 3 and ending with SEQ ID No. 4. Chang et al. teach said antisense compound decreases expression of Kv3.4 in cells (see page 609 and Figure 4). Chang et al. does not teach transplanting transfected cells into the subject or teach transfecting the cells with siRNA targeted to SEQ ID No. 6 or.

Low et al. teach a method of transfecting antisense compounds into cells *ex vivo* using an expression vector and teach transplanting said cells into a subject to be used as a vaccine to inhibit gene expression (see column 4, lines 6-60).

Hammond et al. teach two methods for silencing specific genes: antisense and RNA interference. Hammond et al. teach that although antisense methods are straightforward techniques for probing gene function, the methods have suffered from "...questionable specificity and incomplete efficacy." (see page 110, column 1).

Hammond et al. further teach " "...dsRNAs have been shown to inhibit gene expression in a sequence-specific manner" and further "RNAi is a potent method, requiring only a few molecules of dsRNA per cell to silence expression."

Tuschl et al. teach siRNA molecules which are 21 nucleotides in length and teach said siRNA molecules can be expressed from an expression vector (see page 11). Tuschl et al. teach that siRNAs represent a new alternative to antisense or therapeutics.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a siRNA targeted to a Kv3.4 gene, as taught by Tuschl et al. and Hammond et al. and further it would have been obvious for one of ordinary skill in the art to transfect siRNA into cells *ex vivo* and transplant said cells into a subject to be used as a vaccine to inhibit gene expression, as taught by Low et al.

One would have been motivated to use a siRNA targeted to a Kv3.4 gene instead of an antisense because Hammond et al. teach using siRNA to inhibit gene expression is more sequence specific than using antisense methodologies and RNAi

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using dsRNA is a more potent method requiring only a few molecules of siRNA per cell and Tuschl et al. teach that siRNAs, compared with antisense or ribozyme, provide a new alternative to therapeutic methods of targeting genes. One would have been motivated to transfect cells ex vivo using a siRNA because Low et al. teach transfecting cells can be efficiently transplanted into a subject and work to inhibit gene expression.

Finally, one would have a reasonable expectation of success because Chang et al. teach antisense molecules can be targeted to a Kv3.4 gene and regulate Kv3.4 gene expression which modulates potassium in neuronal ion channels, Hammond et al. and Tuschl et al. teach that of the two methods used for silencing gene function, RNAi using dsRNA is more potent and sequence specific than antisense and finally Low et al. teach efficient transplantation of cells transfecting with an antisense oligonucleotide and one would expect the same success using a siRNA since each molecule is a nucleic acid capable of inhibiting gene expression.

Thus in the absence of evidence to the contrary, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Applicant's Arguments***

#### ***Re: Claim Objections***

The objection of claim 17 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in response to claim amendments filed 12/22/2006.

***Re: Claim Rejections - 35 USC § 112***

The rejection of claims 4, 10 and 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in response to claim amendments filed 12/22/2006.



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### **Conclusion**


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong  
Examiner  
Art Unit 1635

  
JAMES SCHULTZ, Ph.D.  
PRIMARY EXAMINER